K000654

NOV 14 2000

510(k) SUMMARY VBMax

January 31, 2000

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), PreMarket Notification, was in accordance with 21 CFR 807.87.

1. **Submitter of 510(k):**

Company Name:	A-M Systems, Inc. P.O. Box 850, 131 Business Park Loop, Carlsborg, WA 98324
Contact Person	Theodore McDonald, President
Telephone:	1 (360) 683-8300
Fax	1 (360) 683-3525
e-mail	tedm@a-msystems.com

2. **Name of Device**

Trade/Proprietary Name: VBMax Pulmonary Function Filter

Common/Usual Name: Breathing Circuit Bacterial Filter

Classification Name: 21 CFR 868.5260 "Filter, Bacterial, Breathing, Circuit" Class II

3. **Legally Marketed Predicate Devices**

The VBMax Pulmonary Function Filter is substantially equivalent to many legally marketed pulmonary function filters, including those listed in Table 1 below.

TABLE 1

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF THE PREDICATE DEVICES AND THE VBMax® PULMONARY FUNCTION FILTER

Manufacturer	A-M Systems, Inc.	Pulmonary Data Services, Inc.	Bird Life Design
Device	VBMax® Pulmonary Function Filter	KoKo II Pulmonary Function Filter	Barrierflex-PF Pulmonary Function Filter
510(k) Number	Current 510(k)	K934475	K934540
Device Description	Single use, in-line bacterial and viral retention filter with low flow resistance used in the test circuit for pulmonary function testing and which meets ATS* requirements	Single use, in-line bacterial and viral retention filter with low flow resistance used in the test circuit for pulmonary function testing and which meets ATS* requirements	Single use, in-line bacterial and viral retention filter with low flow resistance used in the test circuit for pulmonary function testing and which meets ATS* requirements
Intended Use	Prevents cross contamination of equipment and lessens potential for the spread of infectious disease during pulmonary function testing	Prevents cross contamination of equipment and lessens potential for the spread of infectious disease during pulmonary function testing	Prevents cross contamination of equipment and lessens potential for the spread of infectious disease during pulmonary function testing
Performance Standards	None	None	None

4. **Device Description**

The VBMax Pulmonary Function Filter is a lightweight, single use, inline filter intended to protect patients and equipment from exposure to bacteria and viruses during pulmonary function testing. The device is constructed of a filter layer constructed of a special blend of polymers supported and encased in a Styrene-Acrylonitrile copolymer shell with input and output end connectors sized to accommodate circuit tubing commonly used in the pulmonary function testing laboratory.

Based on the information provided, VBMax Pulmonary Function Filter is substantially equivalent to many legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2000

Mr. Theodore J. McDonald
A-M Systems, Inc.
131 Business Park Loop
Post Office Box 850
Carlsborg, WA 98324

Re: K000654
VBMax® (Pulmonary Function Filter)
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: August 22, 2000
Received: August 24, 2000

Dear Mr. McDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000654
Device Name: VBMAX
Indications for Use:

The VBMax filter is a disposable, single-patient session filter for spirometric and pulmonary function testing. The VBMax filter is designed to prevent bacterial/viral contamination from entering the pulmonary function equipment. The filter is to be used with children and adults subjects, but it is not indicated for use with neonatal subjects. It is to be used under the direction of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000654

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)